DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2015

Coramed Technologies, LLC
Mr. Norman Brunner
Director of RA/QA
6225 W. Howard Street
Niles, IL 60714

Re: K150041
Trade/Device Name: CORA® (Coagulation Resonance Analysis) System
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: May 21, 2015
Received: May 22, 2015

Dear Mr. Brunner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The CORA System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150041

Device Name
CORA Citrated Multichannel Cartridge

Indications for Use *(Describe)*
The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The Citrated Multichannel Cartridge, to be used with the CORA System instrument, contains four independent assays (CK, CRT, CKH and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).
The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.
The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the CORA System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.
The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150041

Device Name
CORA Hemostasis System - Abnormal Wet Quality Control (WQC) Material

Indications for Use *(Describe)*

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample.

The Abnormal Wet Quality Control Material is to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Coramed Technologies, LLC
6225 W. Howard Street, Niles, Illinois 60714
847-647-8800 | 847-510-0502 FAX

CORA® System 510(k) Summary

APPLICANT INFORMATION

Name of Manufacturer: Coramed Technologies, LLC

Manufacturer Street Address: 6225 W. Howard St.

City, State, Zip: Niles, IL 60714

Phone Number: (847) 647-8800

FAX Number: (847) 510-0502

Contact person for all communications: Norman E. Brunner

Email for contact person: nbrunner@coramedtech.com

Date that Summary was prepared: June 23, 2015

DEVICE INFORMATION

Trade name (proprietary name): CORA® (Coagulation Resonance Analysis) System and the following assays and reagents

- Citrated Assays and Reagents
  - CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent
  - CRT (Citrated RapidTEG) (RapidTEG® + $CaCl_2$, for citrated blood) reagent
  - CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent
  - CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent

Common name (usual name): Whole Blood Hemostasis System

Classification Name: 21CFR 864.5425 Multipurpose System for *in vitro* Coagulation Studies

PREDICATE DEVICE

- Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series, K002177, Product Code JPA (System, Multipurpose, for In Vitro Coagulation Studies), Haemoscope Corporation

DESCRIPTION OF THE DEVICE

System Description

The CORA System consists of a four-channel diagnostic analyzer with integrated computer module, system reagents (CK, CRT, CKH, and CFF), and Abnormal Quality Control material and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing. Abnormal Quality Control material is lyophilized and can be reconstituted with water as needed for WQC testing with reagent cartridges.

To perform a test, a disposable CORA Cartridge is inserted into the analyzer. Blood or WQC material is added to an entry port on the cartridge and drawn into the cartridge under analyzer control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for visco-elastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA Measurement Technique

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring) with a diameter of 2.5mm and a length of 4.5mm. Detection of clotting in the CORA System is performed optically. Under control of the analyzer, approximately 20µl of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode.

During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The profile has a maximum amplitude of under 10µm and contains frequencies from 10-500Hz. Some, but not all, of the measurement cell motion will induce motion in the sample meniscus, which will be detected by the photodiode. The resulting motion of the meniscus is monitored optically and recorded by the analyzer to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, it is possible to determine the frequencies of input motion that caused the greatest deflection of the sample (these are called the resonant frequencies).

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from run to run, the CORA System allows direct comparison of elasticity between samples.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change. Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the test tube (ring) and the resonant frequency will rise with increasing firmness of the clot. The

CORA Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot. Results are presented in a format similar to the TEG 5000.

Both the TEG 5000 and CORA System monitor the elastic modulus of clots. Method Comparison testing has been performed, yielding data from approximately 300 patients from three sites (Mayo Clinic, University of Pittsburgh Medical Center, and Sinai Hospital, Baltimore). These data include all applicable parameters from the four citrated tests (CK, CKH, CRT and CFF). The TEG 5000 measures the changes of the linkage forces of the clot between the cup and pin over time, while the CORA System measures the changes of the resonant frequency of the clot over time. Despite the difference in the way the two analyzers measure the changes in the modulus of elasticity of the clot over time, they measure the same physical phenomenon and produce the same result when converted from their specific units of measurement (forces for the TEG5000 and frequency for the CORA System) to millimeters. The fact that these results are similar across all reagents used in both technologies is demonstration that the two technologies measure the same phenomenon, the changes in elastic modulus.

The following definitions apply to calculated parameters in the CORA System:

CORA Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation.	Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics.	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (angle)	Alpha is the angle representing the rate increase in the clot strength and the rapidity of fibrin build-up and cross-linking.	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Assays

The CK assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle), and Maximum Clot Strength (MA). K and Alpha are complementary parameters and should be used in conjunction with Clotting Time (R) and Maximum Clot Strength (MA).

The CRT assay is a semi-quantitative *in vitro* diagnostic assay for monitoring the hemostasis process via both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the CORA System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay is a semi-quantitative *in vitro* diagnostic assay for monitoring hemostasis of 3.2% citrated whole blood specimens in the CORA System after blocking platelet contributions to clot strength. CFF is used in conjunction with CK and clotting characteristics are described by the functional parameter Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

The CKH assay is a semi-quantitative *in vitro* diagnostic assay used in conjunction with the CORA System to monitor the effects of heparin in the blood stream of a patient. CKH is used in conjunction with CK and heparin influence is determined by comparing Clotting Times (R) between the two tests.

Wet Quality Control (WQC)

Abnormal Wet Quality Control (WQC) material consists of bovine plasma with buffers and stabilizers, and is used instead of hypocoagulable blood, in conjunction with the Citrated Multichannel system cartridge. When used with the Citrated Multichannel cartridge, this material provides consistent and repeatable values for CORA parameters to confirm reagent quality and viability.

Abnormal WQC Intended Use

The Abnormal WQC (Wet Quality Control) Material is intended to be used for monitoring the accuracy and precision of tests carried out on the CORA System.

INTENDED USE AND INDICATIONS FOR USE

The CORA System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The CORA System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.

The CORA System provides specific blood modifiers, in the form of reagents dried-in-place within CORA Cartridges.

Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

The indication for CORA System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARING THE CORA SYSTEM TO THE TEG 5000 PREDICATE DEVICE

Table of Similarities

Item	TEG® 5000 Predicate	CORA® System
Analyzer		
Technological Purpose	Monitoring the response of a clot to low levels of applied strain	Monitoring the response of a clot to low levels of applied strain
What is measured	Changes in clot elasticity over time	Changes in clot elasticity over time
Initial Warm Up Time	5 min	5 min
Time to Complete a Test	Varies with assay	Same as TEG 5000
Assays and Reagents		
Intrinsic Contact Activation Reagent (CK)	Kaolin and $CaCl_2$	Kaolin and $CaCl_2$, same materials as TEG 5000

Item	TEG® 5000 Predicate	CORA® System
Intrinsic Contact Activation Reagent with Heparinase for heparin reversal (CKH)	Kaolin and $CaCl_2$ with Heparinase	Kaolin, Heparinase and $CaCl_2$, same materials as TEG 5000
Citrated RapidTEG (CRT) (Tissue Factor and Kaolin Activation)	Tissue Factor (TF), Kaolin and $CaCl_2$	Tissue Factor (TF), Kaolin and $CaCl_2$, same materials as TEG5000
Citrated Functional Fibrinogen (CFF) / Platelet-Blocked (Tissue Factor Activation)	ReoPro® ,Tissue Factor and $CaCl_2$, same materials as CORA	ReoPro®, Tissue Factor and $CaCl_2$, same materials as TEG 5000
Calcium Chloride Reagent (CC) (for re-calcification)	$CaCl_2$ reagent	$CaCl_2$ same materials as TEG 5000
Quality Control Material (WQC Abnormal Control)	TEG coagulation control – Level II	TEG coagulation control – Abnormal, same materials as TEG 5000

Table of Differences

Item	TEG® 5000 Predicate	CORA® System
Analyzer	Thrombelastography analyzer, separate computer and software	Fully integrated Thrombelastography analyzer
Measuring Technique	Direct-contact measurement of shear elasticity of a coagulating sample	Non-contact measurement of shear elasticity of a coagulating sample
Measuring Channels	Two, each independent and interchangeable (can be used with any approved reagent)	Four, each independent and interchangeable (can be used with any approved reagent)
Signal Transducer	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample	Optical detection (silicon photodiode) of the motion of a free surface of the sample
Temperature Control	20° to 40°C	20° to 50°C
Sample Volume (per channel)	360-380 µl	63 µl
Total Reaction Volume (single channel)	360-380 µl	20 µl
Mains Supply Voltage	120V, 60Hz and 220V, 50Hz model available	100-240V, 50-60Hz (international power supply)
Analyzer Input Voltage	24 volts AC, 30 watts max	12 volts DC, 60 watts max
Environment	Level and vibration free position, no solar radiation Operating temperature: 10° to 35 °C Storage Temperature: -30° to +50 °C (analyzer only) Relative humidity 20-80% (non-condensing)	Stable and level surface. Operating Temperature 10° to 32°C Storage Temperature: -20° to 50°C (analyzer only) Relative humidity 20 to 80% (non-condensing)

Item	TEG® 5000 Predicate	CORA® System
Sample Preparation	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample	Performed under analyzer control within the disposable cartridge
Pipetting	Manual accurate pipettes (10, 20, 50, 100, 340, 360, 500, 1000µl)	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge
Consumables	Cups & Pins (acrylic plastic)	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Analytical Precision

Testing was performed in Coramed's laboratory for precision, using CLSI EP5-A2 as guidance. Acceptance criteria for all reagents are: CV ≤ 15% for the R parameter, CV ≤ 25% for the K parameter, and CV ≤ 10% for the Alpha and MA parameters. Three types of donor citrated whole blood (CWB) were used in this precision testing:

- Hypo (donors with natural coagulation levels of R parameter near the upper limit of the reference range and MA parameter near the lower limit of the reference range);
- Normal (donors with natural coagulation levels of R and MA parameters near the center of the reference ranges):
- Hyper (donors with natural coagulation levels of R parameter near the lower limit of the reference range and MA parameter near the upper limit of the reference range

Testing was performed with blood draws from three donors (one Hypo, one Normal, and one Hyper) on each of five days (non-consecutive). Testing was performed by two operators using three reagent lots and twelve analyzers, two replicates. The structure of this precision test is shown below.

Sample Type (Hypo, Normal or Hyper)												
	Day 1 (Total of 5 days)											
Operator	Operator 1						Operator 2					
Reagent lot	1		2		3		1		2		3	
Analyzer	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2	1,2

Structure of Precision Testing

Precision test estimates by test, parameter and donor sample test level are shown in the table on the following page. All acceptance criteria were met.

Test	Parameter	Level	n	Mean	Reagent Lot		Operator*		Analyzer (within Operator, Reagent Lot)		Day (within Analyzer, Operator, Reagent Lot)		Repeatability		Total		Total without Day (Within Day)	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
CFF	FLEV	Hypo	120	269.8	2.36	0.9%	0	0.0%	0	0.0%	5.32	2.0%	5.87	2.2%	8.27	3.1%	6.33	2.3%
CFF	FLEV	Normal	120	376.8	0	0.0%	2.25	0.6%	0	0.0%	5.49	1.5%	3.98	1.1%	7.15	1.9%	4.57	1.2%
CFF	FLEV	Hyper	120	597.4	0	0.0%	0	0.0%	0	0.0%	49.38	8.3%	9.62	1.6%	50.31	8.4%	9.62	1.6%
CFF	MA	Hypo	120	14.8	0.11	0.8%	0	0.0%	0	0.0%	0.29	2.0%	0.33	2.2%	0.45	3.0%	0.35	2.3%
CFF	MA	Normal	120	20.6	0	0.0%	0.13	0.6%	0	0.0%	0.3	1.5%	0.22	1.1%	0.39	1.9%	0.25	1.2%
CFF	MA	Hyper	120	32.7	0	0.0%	0	0.0%	0	0.0%	2.71	8.3%	0.53	1.6%	2.76	8.4%	0.53	1.6%
CKH	R	Hypo	120	8.2	0	0.0%	0	0.0%	0.18	2.2%	0.36	4.3%	0.76	9.2%	0.86	10.0%	0.78	9.5%
CKH	R	Normal	120	6.0	0	0.0%	0.05	0.9%	0.09	1.6%	0.14	2.3%	0.42	7.1%	0.46	7.7%	0.44	7.3%
CKH	R	Hyper	120	4.9	0	0.0%	0.05	1.1%	0	0.0%	0.28	5.7%	0.5	10.0%	0.58	12.0%	0.5	10.0%
CK	Angle	Hypo	120	68.7	0	0.0%	1.09	1.6%	0	0.0%	1.61	2.3%	3.01	4.4%	3.59	5.2%	3.2	4.7%
CK	Angle	Normal	120	72.1	0	0.0%	0	0.0%	0	0.0%	1.14	1.6%	1.73	2.4%	2.07	2.9%	1.73	2.4%
CK	Angle	Hyper	120	76.7	0	0.0%	0	0.0%	0	0.0%	1.84	2.4%	1.77	2.3%	2.56	3.3%	1.77	2.3%
CK	K	Hypo	120	1.8	0.03	1.9%	0.06	3.6%	0	0.0%	0.13	7.2%	0.18	10.0%	0.23	13.0%	0.19	11.0%
CK	K	Normal	120	1.4	0	0.0%	0	0.0%	0	0.0%	0.09	6.7%	0.16	12.0%	0.19	13.0%	0.16	12.0%
CK	K	Hyper	120	0.9	0	0.0%	0	0.0%	0	0.0%	0.12	12.0%	0.18	20.0%	0.22	23.0%	0.18	20.0%
CK	MA	Hypo	120	52.4	0.33	0.6%	0.55	1.0%	0.26	0.5%	0.83	1.6%	0.77	1.5%	1.33	2.5%	1.03	2.0%
CK	MA	Normal	120	59.4	0	0.0%	0.5	0.8%	0.48	0.8%	0.57	1.0%	0.86	1.4%	1.24	2.1%	1.1	1.9%
CK	MA	Hyper	120	68.0	0	0.0%	0.2	0.3%	0	0.0%	0.9	1.3%	0.52	0.8%	1.06	1.6%	0.56	0.8%
CK	R	Hypo	120	8.9	0	0.0%	0.29	3.3%	0	0.0%	0.64	7.1%	0.85	9.5%	1.1	12.0%	0.9	10.0%
CK	R	Normal	120	6.5	0	0.0%	0	0.0%	0	0.0%	0.28	4.3%	0.49	7.6%	0.56	8.7%	0.49	7.6%
CK	R	Hyper	120	5.2	0.13	2.5%	0	0.0%	0	0.0%	0.31	5.8%	0.66	13.0%	0.74	14.0%	0.67	13.0%
CRT	MA	Hypo	120	52.4	0.39	0.7%	0.22	0.4%	0	0.0%	0.92	1.8%	0.59	1.1%	1.18	2.3%	0.74	1.4%
CRT	MA	Normal	120	62.7	0	0.0%	0.15	0.2%	0.14	0.2%	0.37	0.6%	0.31	0.5%	0.52	0.8%	0.37	0.6%
CRT	MA	Hyper	120	69.4	0	0.0%	0	0.0%	0	0.0%	0.91	1.3%	0.2	0.3%	0.93	1.3%	0.2	0.3%

*Operator = Operator + operator-by-reagent lot interaction

In addition, Coramed's Citrated Reagent Precision Protocol Rev. 02 was written to supplement precision data originally provided to FDA in 510(k) K150041. This protocol specifies testing to be performed outside of reference range values but within the Analytical Measurement Range (AMR) limits. This report presents data and statistics resulting from the execution of this protocol.

The following pages contain tables of precision statistics. Table 1 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from normal donors but spiked to achieve hypocoagulable (hypo) and hypercoagulable (hyper) results. Three donors for each reagent-parameter and spiking type were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each donor-reagent-parameter-hypo/hyper type, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B
Sample	Hypercoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1	2	3	4	5	6	7	8	9	10	11	12
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

The focus of this study was on achieving values for the primary coagulation parameters R, MA and FLEV outside the reference ranges but within AMR limits, and taking the resulting K and Alpha (angle) values as is. Total Precision %CV values were all within pre-established limits, except for one CFF MA hypo outcome (11.6% for a limit of 10%) and 2 outcomes for Angle. The K and Angle parameters indicate the kinetics of the clotting process, and are not clinically significant as the main parameters representing coagulation, platelet and fibrinogen activities and abnormalities. The CFF MA CV% is higher because the MA value is small (mean of 6.5 mm) and although the Standard Deviation is very small (0.8mm) the resulting CV% is just over the limit. When the SD is so small there is no clinical significance for the differences making this CV% acceptable.

Table 2 shows standard deviations (StDev) and coefficients of variance (CV) for data using blood samples from patients taking anticoagulants Dabigatran and Warfarin. Four Dabigatran patients and two Warfarin patients for each reagent-parameter were tested using the following structure taken from the protocol. As defined in this structure, there are 12 outcomes for each patient-reagent-parameter, resulting in 48 sets of statistics. Lot-to-lot, Instrument-to-Instrument, Operator-to-Operator, Replicate (Repeatability) and Total Precision statistics are given.

Sample	Hypocoagulable											
Operator	1				2				3			
Reagent Lot	2		3		1		2		1		3	
Instrument	1		2		3		4		5		6	
Replicates	A	B	A	B	A	B	A	B	A	B	A	B

Results for this testing were generally within limits, except for a few minor exceptions. As the data shows, all the MAs, for CK, CRT, and CFF, are within the specified expected CV% across the board while for the R parameter, there are no significant differences between lots, operators and devices and the only CVs (for CK and CKH – R parameter) somewhat exceeding 15% come from repeatability (16.9% for MH-DB003 for CK and 15.9% for MH-DB004 for CKH). Even though the, K and Angle are not parameters that are considered clinically significant the raw data indicates that the single angle CV% that is above the limit was due to an outlier while the K parameter has high CVs due to the fact that elongated coagulation results in higher CVs for that parameter.

Test	**Param**	**Spiking**	**Patient ID**	**N**	**Mean**	**Lot**		**Operator**		**Instrument**		**Repetition**		**Total**	
						StDev	**CV**	**StDev**	**CV**	**StDev**	**CV**	**StDev**	**CV**	**StDev**	**CV**

CK	R	hyper	D101	12	2.1	0	0	0	0	0.1	4.5	0.1	3.1	0.1	5.5
CK	R	hyper	D108	12	2.7	0	0	0	1	0.1	3.5	0.1	2.4	0.1	4.3
CK	R	hyper	D169	12	2.2	0.1	2.8	0	0	0.1	3.1	0.1	2.5	0.1	4.6
CK	R	hypo	D141	12	16.1	0	0	1.1	6.9	1.3	8	0.7	4.3	1.7	10.8
CK	R	hypo	D169	12	15.3	0.8	5.3	0	0	1.6	10.2	1.1	7.1	2	13.2
CK	R	hypo	D108	12	12.1	0.1	1	0.1	0.9	0.9	7.2	0.7	5.6	1.1	9.3
CK	K	hyper	D101	12	0.5	0	0	0	0	0	3.9	0	4.1	0	5.7
CK	K	hyper	D108	12	0.4	0	3.8	0	3.8	0	7.2	0	6.5	0	10.7
CK	K	hyper	D169	12	0.5	0	0	0	0	0	8.2	0	8.2	0.1	11.6
CK	K	hypo	D141	12	3	0.2	5.2	0.2	6	0.3	9.9	0.2	8.2	0.4	14.6
CK	K	hypo	D169	12	3.1	0.5	16.4	0	0	0.5	14.8	0.3	10	0.7	22.7
CK	K	hypo	D108	12	2.2	0	0	0.1	6.4	0.3	12	0.1	6.2	0.3	14.6
CK	Angle	hyper	D101	12	80	0.8	1.1	1.5	1.8	7.2	9	6.9	8.7	10.1	12.6
CK	Angle	hyper	D108	12	85.1	0.1	0.2	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hyper	D169	12	84.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.2	0.2
CK	Angle	hypo	D141	12	54.7	0	0	0	0	8.4	15.4	5.4	9.9	10	18.3
CK	Angle	hypo	D169	12	42.7	1	2.4	1.9	4.5	1.8	4.3	1.6	3.7	3.1	7.2
CK	Angle	hypo	D108	12	66.7	3	4.4	0	0	4.8	7.2	3.3	5	6.3	9.5
CK	MA	hyper	D108	12	71.6	0	0	0.5	0.7	0.3	0.4	0.3	0.4	0.5	0.8
CK	MA	hyper	D169	12	70	0	0	0.1	0.1	0.2	0.2	0.1	0.2	0.2	0.3
CK	MA	hyper	D121	12	71.1	0	0	0	0	0.9	1.3	0.6	0.8	1.1	1.5
CK	MA	hypo	D141	12	42	0.2	0.6	0	0	1.5	3.5	0.9	2.1	1.7	4.1
CK	MA	hypo	D169	12	46.6	0	0	0	0	0.8	1.8	0.5	1.1	1	2.1
CK	MA	hypo	D108	12	45.4	0	0	0.8	1.8	1.2	2.7	0.9	2	1.7	3.7
CKH	R	hyper	D101	12	2	0.1	4.8	0	0	0	2.4	0.1	2.8	0.1	5.5
CKH	R	hyper	D108	12	2.6	0	0	0	0	0.1	2.6	0	1.6	0.1	3.1
CKH	R	hyper	D169	12	2.2	0	0	0	0	0	1.5	0	1	0	1.8
CKH	R	hypo	D141	12	15.7	0	0	1	6.4	0.7	4.5	0.6	4.1	1.3	8.2
CKH	R	hypo	D169	12	14.5	0	0	0.8	5.2	0.8	5.7	0.5	3.2	1.1	7.9
CKH	R	hypo	D108	12	12.3	0.6	5	0	0	0.8	6.3	0.5	4.4	1.1	8.8
CRT	MA	hyper	D108	12	70.8	0.2	0.3	0	0	0.1	0.2	0.1	0.2	0.2	0.3
CRT	MA	hyper	D121	12	72.5	0.2	0.3	0	0	0.4	0.5	0.4	0.5	0.5	0.8
CRT	MA	hyper	D145	12	73	0.2	0.2	0	0	0.2	0.3	0.2	0.2	0.3	0.4
CRT	MA	hypo	D141	12	41.3	0	0	0	0	0.7	1.8	0.5	1.2	0.9	2.2
CRT	MA	hypo	D169	12	44.4	0	0	0.3	0.7	0.6	1.3	0.4	0.9	0.8	1.7
CRT	MA	hypo	D108	12	45.5	0	0	0.4	0.9	1	2.1	0.5	1.1	1.1	2.5
CFF	MA	hyper	D101	12	49.9	0.1	0.1	0	0	0.5	0.9	0.3	0.5	0.5	1.1
CFF	MA	hyper	D141	12	44.3	0	0	0	0	0.5	1.2	0.3	0.6	0.6	1.3
CFF	MA	hyper	D145	12	47	0	0	0	0	0.7	1.4	0.5	1	0.8	1.7
CFF	MA	hypo	D101	12	10.2	0.2	1.5	0	0	0.3	3	0.2	1.7	0.4	3.6
CFF	MA	hypo	D125	12	9.5	0	0	0.2	1.8	0.4	4	0.3	2.7	0.5	5
CFF	MA	hypo	D169	12	6.5	0	0	0.7	10.1	0.3	4.9	0.4	6	0.8	11.6
CFF	FLEV	hyper	D101	12	910.7	1.2	0.1	0	0	8.6	0.9	5	0.5	10	1.1
CFF	FLEV	hyper	D141	12	809	0	0	0	0	9.6	1.2	5.2	0.6	10.9	1.3
CFF	FLEV	hyper	D145	12	858.1	0	0	0	0	11.9	1.4	8.5	1	14.7	1.7
CFF	FLEV	hypo	D101	12	186.4	2.9	1.5	0	0	5.5	3	3.1	1.7	6.8	3.6
CFF	FLEV	hypo	D125	12	173.4	0	0	3.1	1.8	7	4	4.6	2.6	8.7	5
CFF	FLEV	hypo	D169	12	157.5	1.8	1.2	1.1	0.7	2	1.3	1.7	1.1	3.2	2.1

Spiked Precision – Table 1

Test	Param	PatientID	N	Mean	Lot		Operator		Instrument		Repetition		Total	
					StDev	CV	StDev	CV	StDev	CV	StDev	CV	StDev	CV
CK	R	MH-DB001	12	13	0	0	0	0	0.4	3.2	1.2	8.9	1.2	9.4
CK	R	MH-DB002	12	21.3	0	0	0	0	1	4.7	2.1	10.1	2.3	11

CK	R	MH-DB003	12	14.4	0	0	0	0	0	0	2.4	16.9	2.4	16.9
CK	R	MH-DB004	12	11.8	0.5	4	0.5	4.3	0	0	1.6	13.9	1.7	14.8
CK	R	MH-WR001	12	9.9	0.7	7	0.3	2.7	0.3	2.6	0.5	4.9	0.8	8.5
CK	R	MH-WR002	12	10.1	1	10.2	0	0	0.3	3.2	1	10	1.4	13.6
CK	K	MH-DB001	12	1.3	0	0	0	0	0	0	0.2	18.2	0.2	18.2
CK	K	MH-DB002	12	2.4	0	0	0	0	0.4	15.4	1	42	1	44.5
CK	K	MH-DB003	12	1.3	0	0	0	0	0	0	0.3	19.8	0.3	19.8
CK	K	MH-DB004	12	0.9	0.1	11.4	0	0	0	0	0.3	33	0.3	34.4
CK	K	MH-WR001	12	2.2	0	0	0	0	0	0	0.2	8.2	0.2	8.2
CK	K	MH-WR002	12	2	0	0	0	0	0	0	0.4	19.1	0.4	19.1
CK	Angle	MH-DB001	12	72.5	0	0	0	0	0	0	3.6	5	3.6	5
CK	Angle	MH-DB002	12	55.5	0	0	0	0	10.3	18.6	11.6	20.8	15.2	27.4
CK	Angle	MH-DB003	12	72.7	0	0	0	0	0	0	3.2	4.3	3.2	4.3
CK	Angle	MH-DB004	12	79.5	0	0	0	0	0	0	3.4	4.3	3.4	4.3
CK	Angle	MH-WR001	12	65	0	0	0	0	0	0	1.1	1.7	1.1	1.7
CK	Angle	MH-WR002	12	67.1	0	0	1.1	1.6	0	0	3	4.4	3.1	4.6
CK	MA	MH-DB001	12	60.2	0	0	0	0	0	0	0.9	1.5	0.9	1.5
CK	MA	MH-DB002	12	64.5	0	0	0.2	0.4	0	0	0.6	1	0.7	1
CK	MA	MH-DB003	12	64.1	0	0	0.4	0.7	0	0	0.5	0.8	0.7	1
CK	MA	MH-DB004	12	71.9	0.1	0.1	0.5	0.6	0	0	0.5	0.7	0.7	0.9
CK	MA	MH-WR001	12	60.6	0	0	0	0	0	0	0.9	1.4	0.9	1.4
CK	MA	MH-WR002	12	59.7	0	0	0	0	1	1.6	0.8	1.3	1.2	2
CKH	R	MH-DB001	12	12.2	0.8	6.8	0	0	0	0	0.7	5.8	1	8.2
CKH	R	MH-DB002	12	19.3	0	0	1.6	8.4	0	0	2.2	11.4	2.6	13.5
CKH	R	MH-DB003	12	13.5	0	0	0.5	4	0	0	1.4	10.6	1.5	11.1
CKH	R	MH-DB004	12	11.3	0	0	0	0	0	0	1.8	15.9	1.8	15.9
CKH	R	MH-WR001	12	8.4	0	0	0.1	0.8	0	0	0.8	9.7	0.8	9.8
CKH	R	MH-WR002	12	9.1	0.5	5.1	0	0	0	0	0.7	7.4	0.8	8.6
CRT	MA	MH-DB001	12	64.9	0.1	0.1	0	0	0.1	0.1	0.1	0.2	0.1	0.2
CRT	MA	MH-DB002	12	67.7	0.1	0.1	0	0	0	0	0.2	0.2	0.2	0.2
CRT	MA	MH-DB003	12	66	0	0	0	0	0	0	0.1	0.2	0.1	0.2
CRT	MA	MH-DB004	12	73.8	0.1	0.1	0	0	0.1	0.1	0.2	0.2	0.2	0.3
CRT	MA	MH-WR001	12	64	0.1	0.1	0	0	0	0	0.2	0.3	0.2	0.3
CRT	MA	MH-WR002	12	64.7	0	0	0	0	0	0	0.3	0.4	0.3	0.4
CFF	MA	MH-DB001	12	20.7	0.1	0.4	0	0	0.3	1.3	0.1	0.6	0.3	1.4
CFF	MA	MH-DB002	12	23.7	0.3	1.3	0.3	1.4	0	0	0.2	0.7	0.4	1.6
CFF	MA	MH-DB003	12	23.4	0.2	1	0	0	0	0	0.3	1.5	0.4	1.7
CFF	MA	MH-DB004	12	51.9	1.1	2.2	0	0	0	0	0.4	0.8	1.1	2
CFF	MA	MH-WR001	12	20.7	0	0	0	0	0	0	0.4	1.7	0.4	1.7
CFF	MA	MH-WR002	12	24.7	0.1	0.4	0.3	1.2	0	0	0.3	1.3	0.4	1.7
CFF	FLEV	MH-DB001	12	377.3	1.4	0.4	0	0	4.8	1.3	2.4	0.6	5.3	1.4
CFF	FLEV	MH-DB002	12	432.2	5.8	1.3	6.2	1.4	0	0	3	0.7	6.8	1.6
CFF	FLEV	MH-DB003	12	426.5	4.5	1	0	0	0	0	6.2	1.5	7.3	1.7
CFF	FLEV	MH-DB004	12	947.1	20.9	2.2	0	0	0	0	7.5	0.8	19.3	2
CFF	FLEV	MH-WR001	12	377.4	0	0	0	0	0	0	6.5	1.7	6.5	1.7
CFF	FLEV	MH-WR002	12	450	1.6	0.4	5.2	1.2	0	0	6	1.3	7.7	1.7

Patient-Derived Hypo Samples (Dabigatran and Warfarin) – Table 2

Interference

Testing was performed in Coramed's laboratory for interference, using CLSI EP7-A2 as guidance.

For CK, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Only Hemolysis and Hemodilution were found to be interferents.

For CRT, potential interferents tested were Absence of a Discard Tube, Short Draw, Hemolysis, Hemodilution and epsilon aminocaprioc acid (EACA). Short Draw, Hemolysis and Hemodilution were found to be interferents.

For CKH, Protamine was tested for interference. Protamine was found to be an interferent for CKH at concentrations above 0.062 mg/ml.

For CFF, potential interferents tested were Na Heparin and Hemodilution. Heparin was found to be an interferent for CFF above Heparin concentrations of 1 IU/ml, and Hemodilution was found to be an interferent above hemodilution levels of 30%.

Linearity

Testing was performed in Coramed's laboratory for linearity, using CLSI EP6-A as guidance.

CFF was tested and found to be linear with varying concentrations of Fibrinogen (RiaSTAP) added. These concentrations ranged from 0 mg/dl to 565.5 mg/dl, over an FLEV range of 156 mg/dl to 1145 mg/dl. This corresponds to an MA range of 8.5 mm to 62.7 mm.

Sensitivity and Specificity

CK was tested for Sensitivity and Specificity with respect to Na Heparin, comparing R parameters of five blood samples with different clinically relevant concentrations of Heparin to five samples without heparin. Both Sensitivity and Specificity were found to be 100%.

Heparin Neutralization

Heparin Neutralization of CKH was tested using blood samples spiked with Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) and comparing these results to data obtained from testing CK with un-spiked blood samples. CKH was found to completely neutralize UFH levels of 5 IU/ml blood and LMWH levels of 0.013 mg/ml blood.

SUMMARY OF CLINICAL PERFORMANCE DATA

Testing was performed at three clinical sites for Reference Ranges and Method Comparison.

Reference Ranges

Reference Ranges for the CORA assays were estimated using the CLSI C28-A3c Guideline on three reference sample groups. Blood samples from up to 55 normal volunteer subjects were taken at each of the three sites, for a total of 157 samples. There were at least 151 valid results for every parameter for all reagents. Samples were excluded on a per-parameter basis using standard outlier criteria. An alternative method would have been to exclude all parameters for any tests where one or more parameter results were determined to be outliers. However, it was decided to retain all valid parameter results in calculating reference ranges because a larger number of samples adds statistical credibility. Also, it does not appear that using the alternative approach would have any significant effect on the reference ranges. Subjects were chosen representing demographic populations of the three areas, regarding age, race and gender. These reference ranges are shown below.

Reagent ↓	N	R (min)	N	K (min)	N	Angle (deg)	N	MA (mm)	N	FLEV (mg/dl)
CK	157	4.6-9.1	157	0.8-2.1	155	63 - 78	151	52 - 69		
CRT							152	52 - 70		
CKH	155	4.3-8.3								
CFF							151	15 - 32	152	278-581

Reference Ranges for CKH are shown but not usually required because the only purpose is to neutralize the heparin in a patient's blood, regardless of the patient's hemostasis condition. Comparing results from the CK and CKH tests for the R parameter can assist in determining whether or not there is heparin in the blood sample.

Reference Ranges for Wet Quality Control (WQC) Abnormal material when used in CORA assay cartridges were estimated. Using three lots of Abnormal Quality Control and three citrated reagent lots, a total of over 135 test results were obtained.

Reagent ↓ & Abnormal WQC (AWQC)	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)
CK - AWQC	0.8 - 1.5	0.6 - 0.8	75 - 83	32 - 47	
CRT – AWQC				32 - 46	
CKH – AWQC	0.8 - 1.5				
CFF – AWQC				30 - 60	563-873

Method Comparison

Method Comparison studies were conducted at three clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing cardiovascular surgery or cardiology procedures, with blood samples drawn pre- and post-surgery and in the ICU. In order to broaden the range of comparison, up to 10% contrived samples were added. Summary statistics are presented below.

Method Comparison Statistics Summary – All Clinical Sites					
Parameter	**R**	**Intercept**	**95% CI**	**Slope**	**95% CI**
CK – R (min)	0.868	-0.325	-0.425	1.069	1.034
			-0.225		1.103
CK – K (min)	0.740	-0.097	-0.292	0.906	0.769
			0.098		1.042
CK – Alpha (deg)	0.680	7.305	-13.160	0.940	0.640
			27.769		1.240
CK – MA (mm)	0.924	2.351	0.166	0.948	0.912
			4.536		0.983
CKH – R (min)	0.812	-0.329	-0.393	1.057	1.026
			-0.265		1.089
CRT|CK – MA (mm)	0.929	-0.126	-1.909	0.978	0.948
			1.656		1.007
CFF – MA (mm)	0.938	-0.774	-1.836	1.126	1.072
			0.289		1.180
CFF – FLEV (mg/dl)	0.928	-12.495	-36.810	1.127	1.059
			11.819		1.194

In addition, a Reader Study was conducted to assess the comparison of CORA System and TEG 5000 results based on reading printed test outcomes. The study was performed at three sites, using three experienced TEG 5000 doctors as readers at each site, for a total of nine readers. 30 test outcomes were compared for each of the reagent test categories, for a total of 270 reading comparisons per reader. Excellent agreement between the two devices was demonstrated.

In both the Method Comparison Study and Reader Study, the CORA RapidTEG (CRT) MA parameter was compared to the TEG 5000 Kaolin (CK) MA parameter, to demonstrate that the CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTING

The data and information provided in this submission support a substantial equivalence determination for the CORA System and the TEG 5000 predicate device.